

WHAT IS CLAIMED IS:

1. A prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising:
  - a valve having a plurality of resilient leaflets;
  - a valve support configured to be collapsible for transluminal delivery and comprising a first and a second portion, said first portion expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned, said second portion supporting the base and the commissure points of the valve; and
  - a radial restraint for controlling a diameter of the second portion.
2. The valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter.
3. The valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting collapse below a preset diameter.
4. The valve assembly of Claim 1, wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter.
5. The valve assembly of Claim 1, wherein the radial restraint comprises a wire.
6. The valve assembly of Claim 1, wherein the radial restraint comprises a thread.
7. The valve assembly of Claim 1, wherein the radial restraint comprises a mechanical stop.
8. The valve assembly of Claim 1, wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter.
9. The valve assembly of Claim 8, wherein the material comprise shape memory material.
10. The valve assembly of Claim 1, wherein the radial restraint comprises a cuff.
11. The valve assembly of Claim 1, wherein the radial restraint comprises a stent configured to cooperate with the valve support so as to substantially preclude recoil.
12. The valve assembly of Claim 1, further comprising a drug-eluting component.

13. The valve assembly of Claim 1, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment.

14. The valve assembly of Claim 1, wherein the valve support comprises at least one wire.

15. The valve assembly of Claim 14, wherein the valve support comprises a single length of wire.

16. The valve assembly of Claim 14, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force.

17. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support permitting attachment thereto of the base and the commissures of the valve, and an anchor for engaging the lumen wall when expanded for preventing substantial migration of the valve assembly when positioned in place;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

18. The method of Claim 17, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

19. The method of Claim 17, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

20. The method of Claim 17, further comprising the step of advancing a blood pump across the deficient native valve.

21. The method of Claim 20, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.
22. The method of Claim 20, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.
23. The method of Claim 20, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.
24. The method of Claim 18, further comprising the steps of:  
advancing a stent from the second vascular access site to the deficient valve;  
deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.
25. The method of Claim 17, wherein the valve support and anchor are self-expanding.
26. The method of Claim 25, further comprising the step of restraining self-expansion of the valve support to a preset diameter by at least one radial restraint
27. The method of Claim 17, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.
28. The method of Claim 17, wherein the catheter comprises a filter for catching emboli or valve fragments.
29. The method of Claim 17, wherein the catheter comprises an over-the-wire catheter.
30. The method of Claim 17, wherein the catheter comprises a rapid exchange catheter.
31. A prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve, the valve assembly comprising an axial valve support portion configured to support a prosthetic valve having at least one leaflet and to prevent substantial interference with the positioning and/or operation of the prosthetic valve by any residual components of the native valve, including calcified native components, said support portion comprising at least one radial restraint at a first section of said support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic valve leaflets and to prevent significant regurgitation.

32. The valve assembly of Claim 31, wherein the radial restraint is configured to reduce recoil.

33. The valve assembly of Claim 31, wherein the radial restraint comprises a mechanical stop.

34. The valve assembly of Claim 31, wherein the support portion further comprises a second section configured to expand in situ for pushing the residual native valve components against the native annulus and surrounding tissue.

35. The valve assembly of Claim 34, wherein the second section is configured to expand to a diameter different from that of the first section.

36. The valve assembly of Claim 34, wherein said second section is configured to be expanded by a balloon catheter.

37. The valve assembly of Claim 36, wherein said second section is configured to be expanded beyond its yield point in situ.

38. The valve assembly of Claim 31, further comprising a stent configured to expand in situ for pushing against the residual native valve components.

39. The valve assembly of Claim 38, wherein the stent is self-expanding.

40. The valve assembly of Claim 38, wherein the stent is configured to be expanded by a balloon catheter.

41. The valve assembly of Claim 31, further comprising a stent configured to reduce the recoil of the support portion following self-expansion of the support portion.

42. The valve assembly of Claim 38, wherein the stent is configured to reside within the valve support portion when deployed.

43. The valve assembly of Claim 38, wherein the stent is configured to reside outside the valve support portion when deployed.

44. The valve assembly of Claim 31, further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration.

45. The valve assembly of Claim 31, wherein said radial restraint comprises a wire.

46. The valve assembly of Claim 31, wherein said radial restraint comprises a thread.

47. The valve assembly of Claim 31, wherein said radial restraint comprises a cuff.

48. A method of replacing a deficient native valve comprising the steps of:

providing a prosthetic valve assembly, the assembly comprising a valve, a valve support comprising a first valve support section permitting attachment thereto of the base and the commissures of the valve, and a second valve support section configured to expand in situ to push the residual native valve components against the native annulus and surrounding tissue;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

49. The method of Claim 48, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

50. The method of Claim 48, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

51. The method of Claim 48, further comprising the step of advancing a blood pump across the deficient native valve.

52. The method of Claim 51, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.

53. The method of Claim 51, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.

54. The method of Claim 51, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.

55. The method of Claim 48, further comprising the steps of:  
advancing a stent from the second vascular access site to the deficient valve;  
deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.

56. The method of Claim 48, wherein the valve support is self-expanding.

57. The method of Claim 56, further comprising the step of restraining self-expansion of a portion of the valve support to a preset diameter by at least one radial restraint

58. The method of Claim 49, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.

59. The method of Claim 48, wherein the catheter comprises a filter for catching emboli or valve fragments.

60. The method of Claim 48, wherein the catheter comprises an over-the-wire catheter.

61. The method of Claim 48, wherein the catheter comprises a rapid exchange catheter.

62. A method of replacing a deficient native valve comprising the steps of:  
providing a prosthetic valve assembly, the assembly comprising a valve, a valve support permitting attachment thereto of the base and the commissures of the valve, and a radial restraint controlling a diameter of at least a portion of the valve assembly;

collapsing the valve support to fit within a distally positioned sheath on a catheter;

inserting a guidewire into a vascular access site;

externalizing at least a portion of the guidewire through a second vascular access site;

advancing the catheter over the guidewire to the deficient native valve;

deploying the valve assembly; and

withdrawing the catheter, leaving the valve assembly to function in place of the deficient native valve.

63. The method of Claim 62, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the first vascular access site.

64. The method of Claim 62, wherein the step of advancing the catheter comprises advancing the catheter to the deficient native valve from the second vascular access site.

65. The method of Claim 62, further comprising the step of advancing a blood pump across the deficient native valve.

66. The method of Claim 65, wherein the step of advancing the catheter comprises advancing the catheter over the blood pump.

67. The method of Claim 65, wherein the step of advancing the blood pump comprises inserting the blood pump across the first vascular access site.

68. The method of Claim 65, wherein the step of advancing the blood pump comprises inserting the blood pump across the second vascular access site.

69. The method of Claim 64, further comprising the steps of:

advancing a stent from the second vascular access site to the deficient valve;

deploying the stent to substantially preclude any portion of the native valve from obstructing blood flow.

70. The method of Claim 62, wherein the valve support is self-expanding.

71. The method of Claim 62, wherein the valve assembly further comprises loop elements for releasably attaching the anchor to the catheter.

72. The method of Claim 62, wherein the catheter comprises a filter for catching emboli or valve fragments.

73. The method of Claim 62, wherein the catheter comprises an over-the-wire catheter.

74. The method of Claim 62, wherein the catheter comprises a rapid exchange catheter.

75. A prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve, the valve assembly comprising a non-cylindrical valve support and at least one anchor.

76. A method of replacing a deficient heart valve comprising the steps of:  
delivering to a target native valve site a valve prosthesis comprising a first portion and a second portion, the first portion limited in its expansion diameter when compared to the second portion;  
delivering a perfusion pump to the desired target site to pump blood through the target site during application of the valve prosthesis; and  
deploying the valve prosthesis while pumping blood through the target site.

77. The method of Claim 76, wherein the valve prosthesis further comprises a radial restraint.

78. The method of Claim 76, wherein the valve prosthesis further comprises an anchor.